to incorporate same language required by the Examiner (declaration point 2) to expedite prosecution.

> The deposited material will remain available to the public for a period of at least five years after the most recent request for a sample of the deposited microorganism, for at least thirty (30) years following the date of deposit, and for at least the enforceable life of the patent, whichever of these is longer.

The declaration is revised simply to incorporate the deposit term requested by the Examiner. The declaration now fully complies with the requests set forth in MPEP 2408. Accordingly, withdrawal of the rejection based on 35 U.S.C. 112, first paragraph is respectfully requested.

III. The Rejections to Claims 9 and 13 under 35 U.S.C. 112, first paragraph

The Examiner raises a new matter objection to claims 9 and 13. In response to Applicants' amendment filed on September 20, 2001, the Examiner takes the position that the specification does not support the revised claims. Particularly, the Examiner indicates that the amended claim language, referring to the claimed species "FERM BP-2998", is not supported by pages 10-11 of the specification pointed out by the Applicants. The Applicants disagree with this position.

The Applicants respectfully direct the Examiner's attention to the phrase "hPM-1" at page 11, line 1. PM-1 is a reshaped human antibody as disclosed by the specification in an example of using PM-1 in the present invention. The phrase "PM-1" is again mentioned at page 18, line 9 and line 28, respectively as an embodiment example.

The Applicants further respectfully direct the Examiner's attention to the page 6, lines 19-29 of the present specification:

> Examples of such antibodies which are IL-6 antibodies include MH166 (Matsuda et al., Eur. J. Immunol. 18:951-956, 1988) and SK2 antibody (Sato et al., Journal for

the 21st General Meeting of the Japan Immunology Association, 21:116, 1991). Examples of IL-6R antibodies include **PM-1 antibody** (deposited on July 12, 1989 at the Patent and Bio-Resource Center, National Institute of Advanced Industrial Science and Technology, Chuo No. 6, 1-1, Higashi 1 chome Tsukuba-shi, Ibaraki-ken 305-5466, Japan, **as FERM BP-2998**) (Hirata et al., J. Immunol. 143:2900-2906, 1989), AUK12-20 antibody, AUK64-7 antibody and AUK146-15 antibody (Intl. Unexamined Patent Application No. WO92-19759). An example of gp130 antibody is AM64 antibody (Japanese Unexamined Patent Publication 3-219894). (emphasis added)

The Applicants note that the cited paragraph was added into the original specification in response to the objection to claims 9-17 in the first office action. The cited paragraph shows that the PM-1 hybridoma deposited according to the Budapest Treaty was indexed as FERM BP-2998. The disclosure of the term on page 11, in its context, clearly refers to the FERM BP-2998 aforementioned.

Accordingly, the Applicants respectfully disagree that the specification on pages 10-11 discloses only a genus. The present specification fully supports the presently claimed FERM BP-2998, and fully enables a person skilled in the art at the time the application was filed. Thus, withdrawal of this new matter rejection is respectfully requested.

IV. The Rejections to Claims 9-17 under 35 U.S.C. 112, first paragraph

The Examiner rejects claims 9-17, as the specification is allegedly not enabling with respect to the claim language "a complementary determining region (CDR)." The Examiner indicates that an antibody comprising just a single functional CDR would be highly unpredictable. In addition, citing Bending, page 86, column 2, the Examiner states that, even if all CDRs are placed in the framework of the most closely related antibody as is possible, the resultant antibodies often "will show little or no biding to antigen." Based on

these two premises, the Examiner concludes that undue experimentation must be taken to obtain the claimed subject matter.

Without contesting the correctness of the Examiner's conclusion, the Applicants have amended claims 9 and 13. The Applicants have changed the phrase "a complementary determinant region" to "a set of complementarity determining regions." As is well known in the art, the term "a set of complementarity determining regions" refers to a set of three complementary determinants contained in one chain of an antibody molecule.

Furthermore, without contesting the correctness of the assertion made in Bending, the Applicants respectfully draw the Examiner's attention to the first, and the second full paragraphs of column 2, on page 86. Bending alleged that if no further modification step is taken, such a simple CDR graft often "will show little or no binding to the antigen," while certain further modifications are required for achieving a "good binding to antigen," without clearly defining the **subjective** term "good."

Applicants note that an antibody with low affinity may still be patentably useful (e.g., administered at higher doses, it may well be effective). However, Bending does not indicate whether routine experiments would make any improvement to the binding ability of the CDR graft. In other words, the Examiner jumps to a conclusion not supported by Bending.

In addition, the Examiner adopts a presumption inconsistent with the patent law. The Examiner wrongly assumes that the claimed subject matter must achieve "good" performance. The Examiner does not recognize that the claimed subject matter can be practiced without undue experimentation, which is sufficient to satisfy the requirements of patentability.

As such, since the Examiner's position is not supported by the cited reference, and the presumption taken by the Examiner contradicts section 112, withdrawal of the rejection is respectfully requested.